Dose display mechanism for a drug delivery device

This invention relates to a dose display mechanism for a drug delivery device that allows the user to select multiple doses of an injectable drug and for the dispensing of the set dosage of the drug and applying said drug to a patient, preferably by injection. In particular, the present invention relates to such devices, which are handled by the patients themselves.

Drug delivery devices, which allow multiple dosing of the required dosage of liquid drug and administration of the liquid to a patient, are well known in the art. Generally, such devices have substantially the same purpose as that of an ordinary syringe.

Pen-type injectors of this kind must meet a number of requirements to meet user needs. These devices need to be robust in construction, yet easy to use both in terms of the manipulation of the parts and understanding by a user of its operation. In the case of those with diabetes, many users will be physically infirm and may also have impaired vision. Where the injector is to be disposable rather than reusable, the injector should be cheap to manufacture and easy to dispose of (preferably being suitable for recycling).

WO 01/87386 A1 teaches a mechanical dose display for a medicine administration device consisting of at least one flexible disk which is driven by the dose setting actuator and which carries a band of numbers along its parameter. By folding the disc in such a way that the diametrical opposite points of the parameter just meet, allows each digit along the parameter to be about three times as high as corresponding digits written on a drum having a diameter corresponding to the diameter of the tube formed by the folded disc. Through the addition of a second disc it is possible to show a two-digit number.

WO 98/10813 A1 discloses a dose setting mechanism by which doses are indicated on a clock dial having a first part secured to the housing and a second part which is rotatable relative to the first part and which is coupled to the dose setting element. One

of the parts carries the scale and the other carries an indicating member indicating a point on the scale. By using a clock dial the dial can be made arbitrarily large being limited only by the fact that the device must not be too bulky.

US 5279585 A discloses an injection device for injecting fluids such as insulin within body tissue. The dose setting means of the device includes a units counter ring, a tens counter ring positioned in adjoining relation to the units counter ring, and a transmission means connecting the units counter means and the tens counter ring.

Accordingly, the problem to be solved by instant invention is to provide a dose display that displays in clear and large indices, i.e. numbers, symbols, letters, etc., the set dose and is suitable for use by visually disabled users, particularly for use with pen-type drug delivery devices.

A first aspect of instant invention is to provide a dose display mechanism for a drug delivery device comprising:
a dose setting dial having an external thread and external grooves extending from the proximal end to the distal end; and
a counter ring in interlocking relationship with the external grooves of the said dose setting dial such that said counter ring is free to move axially along said external grooves with respect to the said dose setting dial whilst being prevented from rotation with respect to the said dose setting dial.

It is a second aspect of instant invention to provide a drug delivery device comprising a) a drive mechanism and b) the dose display mechanism of instant invention.

It is a third aspect of instant invention is the use of a dose display mechanism according to the invention in a method of assembling a device according to the invention.

A fourth aspect of instant invention is the use of a device according to the invention for the administration of a pharmaceutical formulation to the human or animal body.

Another aspect of instant invention is a method of assembling a drug delivery device according to the invention, comprising the step of mounting the mechanism according to the invention to any components in order to assemble a drug delivery device.

The terms, which are used in order to define instant invention, are generally to be understood in accordance with the general knowledge of the person skilled in the art. Further, the following terms shall have the following, optionally preferred, meaning in accordance with instant invention:

The term "drug delivery device" according to instant invention shall preferably mean a multi-dose, disposable, mobile, hand-held device designed to dispense a selected dose of medicament, e.g. insulin, insulin analogues, growth hormones, low molecular heparins, and their derivatives etc., optionally suitable for self-administration. Said device is usually of the mechanical type. More preferred, the term "drug delivery device" shall mean a disposable, multi-dose, pen-type device having mechanical dose delivery and dose selection mechanisms designed for regular injection by persons without formal medical training, e.g., patients.
Usually, the "drug delivery device" of instant invention comprises a cartridge, which contains a pharmaceutical formulation, which can be administered via a needle, and, optionally a cartridge holder.

The term "pharmaceutical formulation" shall preferably mean a liquid or suspension or the like contained in the cartridge, comprising a drug or vaccine. The drug may contain one or more proteins, peptides, or small molecules, which may be administered subcutaneously. Preferably, the drug is one or more hormone or antithrombotic, especially selected from the group consisting of insulines, heparines, derivatives, analogous, and substitutes thereof.

The term "dose setting dial" according to instant invention shall preferably mean an essentially tubular component of essentially circular cross-section having an external thread engaged with the housing by means of a first screw structure, allowing the dose setting dial to rotatably move towards the proximal end during dose setting and

rotatably move towards the distal end during dose dispensing. The "dose setting dial" according to instant invention is designed to indicate a selected dose of the dispensable pharmaceutical formulation. This may be achieved by use of markings, symbols, numerals, etc., e.g., printed on the external surface of the dose setting dial. Additionally, the dose setting dial may be releasibly connected to the inner cylinder by a clutch means. To set the dose, the dose setting dial may be rotated and the dose setting dial and the inner cylinder rotate together towards the proximal end. During dose dispensing, the clutch means may disengage the dose setting dial from the inner cylinder, such that the dose setting dial may rotate relative to the inner cylinder towards the distal end. Further, the dose setting dial may comprise one or more stops to limit the maximum amount of a single dose.

The term "inner cylinder" according to instant invention shall preferably mean any essentially tubular component of essentially circular cross-section, releasibly connected to the dose setting dial, such that relative rotation between said dose setting dial and said inner cylinder is prevented during dose setting but is allowed during dose dispensing. In a preferred embodiment the inner cylinder is further engaged with the piston rod by means of a free lock. During dose dispensing the inner cylinder is disengaged from the dose setting dial by a clutch means and is moved towards the distal end without rotation (with respect to the housing).

The term "releasibly connected" according to instant invention shall mean that two components of the instant mechanism or device are reversibly joined with each other, allowing coupling and decoupling. This is achieved, e.g., by a clutch means.

The term "clutch means" according to instant invention shall mean any means, which releasibly connects the dose setting dial and the inner cylinder and which is designed to allow rotation of the dose setting dial and the inner cylinder with respect to the housing when the dose setting dial and the inner cylinder are coupled and, when both are de-coupled, allows rotation of the dose setting dial with respect to the housing, but does not allow rotation of the inner cylinder with respect to the housing and allows axial movement of the inner cylinder. Accordingly, the term "clutch means" is any

clutch engaging for the purpose of reversibly locking two components in rotation, e.g., by use of axial forces to engage a set of face teeth (saw teeth, dog teeth, crown teeth) or any other suitable frictional faces.

The term "counter ring" according to instant invention shall preferably mean a component, which is in an interlocking relationship to the dose setting dial. In a preferred embodiment, the counter ring is assembled concentrically on the outer circumference of the dose setting dial (essentially circular shape), optionally adjacent to the front side (at the distal end) of the threaded insert [screw lead].

In another preferred embodiment, a positioning means is provided to prevent the counter ring from axial movement with respect to the housing during dose setting and dose dispensing, but allowing rotational movement of the counter ring with respect to the housing during dose setting and dose dispensing. This may be achieved by assembling a positioning collar on the outer circumference of the dose setting dial adjacent to the distal end of the counter ring, which is optionally integrated into the housing.

The "counter ring" shall serve to indicate one digit of the amount of the set dose by means of indices along its outer circumference, whereas one or more further indices of the set dose are indicated along the outer circumference of the dose setting dial. Preferably, dialling of the "counter ring" shall enable the smallest increments of the dose (e.g., tens, eights, quarters, or halves of a unit, or single units) to be set.

The term "interlocking relationship" according to instant invention shall mean any constructive connection of the counter ring and the dose setting dial, which allows both, the counter ring and the dose setting dial, to rotate together with respect to the housing, preferably by means of a screw structure (e.g., thread, groove, rib), and also allows longitudinal axial movement of the dose setting dial with respect to the counter ring, when the dose setting dial is moved (either towards the proximal end or the distal end). Preferably, the counter ring remains visible in the display window and displays the set dose (amount of drug), when the dose setting dial is screwed out in order to set the dose.

The term "drive mechanism" according to instant invention shall mean any mechanism (e.g., lead screw, rack and pinion, gear box), which allows force transmission from the proximal to the distal end of a drug delivery device for the purpose of dispensing a pharmaceutical and which is engaged with the dose dialing mechanism of instant invention.

The term "housing" according to instant invention shall preferably mean an exterior or interior ("insert") cover. The housing may be designed to enable the safe, correct, and comfortable handling of the drug delivery device (e.g., the drive mechanism). Usually, it is designed to house, fix, protect, guide, and/or engage with the inner mechanism(s) or components of the drug delivery device (e.g., the drive mechanism) by limiting the exposure to contaminants, such as liquid, dust, dirt etc. In general, the housing may be unitary or a multipart component of tubular or non-tubular shape.
Preferably, the "housing" is designed to contain a cartridge and optionally a cartridge holder, which is preferably mounted at the distal end of the housing.

The term "engaged" according to instant invention shall mean the interlocking of two or more components of the dose display mechanism/drug delivery device, preferably the interlocking of screw structures of components.

The term "screw structure" according to this application shall mean a full or part thread, e.g., a cylindrical spiral rib/groove located on the internal and/or external surface of a component of the drug delivery device, having an essentially triangular or square or rounded section designed to allow continuous free rotational and/or axial movement between components. Optionally, a screw structure may be further designed to prevent rotational or axial movement of certain components in one direction.

The term "plunger rod" according to this application shall mean a component of the drive mechanism, which is adapted to operate through/within the housing, designed to transfer forces from the proximal end to the distal end of the drug delivery device, preferably to the cartridge piston, for the purpose of drug dispensing.

The term "distal end" according to instant invention shall mean the end of the device or a component of the device, which is closest to the dispensing end of the device.

The term "proximal end" according to instant invention shall mean the end of the device or a component of the device, which is furthest away from the dispensing end of the device.

The term "lead screw" according to instant invention shall mean any essentially cylindrical component, which is engaged with the plunger rod, preferably threadedly engaged, and rotates with respect to the plunger rod when moving towards the proximal direction during dose setting, and moving axially towards the distal end without rotation during dose dispensing. In a preferred embodiment, the lead screw is further engaged with a free lock, (e.g., a friction clutch, a thrust bearing or the like), preferably threadedly engaged.

The term "free lock" shall mean an essentially cylindrical component, which is engaged between the inner surface of the inner cylinder and the lead screw, preferably at the proximal end of the lead screw. The "free lock" rotates and moves axially relative to the inner cylinder by means of a screw structure.
The free lock is rotatable relative to the lead screw, whilst movement of the free lock in the axial direction is not possible with respect to the lead screw.

The term "display window" according to instant invention shall mean any opening in the housing, e.g. a hole, or a transparent section in the housing, which allows the status of the device to be displayed, preferably, the status of dose setting, particularly, the amount of set dose. This may be achieved by means of a dose indicator, which exhibits one or more numerical and/or graphical symbols, values and/or characters, preferably two or three digits, in order to indicate the set dose. In another preferred embodiment, the "display window" displays the value of the selected dose consisting of one or more digits indicated along the outer circumference of the counter ring, and one or more digits indicated along the outer circumference of the dose setting dial. In another embodiment, the display window is located essentially at the proximal end of

the device.

The present invention describes a dose display mechanism consisting of a dose setting dial and a counter ring each displaying indices on their outer circumference arranged such that a two-indices representation of the selected dose can be displayed. By such an arrangement it is possible to maximise the size of the indices of the display, thus making it suitable for use by visually impaired users.

The invention is described in further detail with reference to the following figures:
FIG. 1 is a perspective view of the counter ring in position on the dose setting dial.
FIG. 2 is a schematic showing the numerical value of the first digit of the counter ring (a) and a perspective view of the counter ring (b).
FIG. 3 is a schematic showing the numerical value of the second digit of the dose setting dial.
FIG. 4 is a perspective view of the entire device indicating the display window.
FIG. 5 is a sectional side view illustrating a dose setting operation of the device.

Figure 1 shows a perspective view of the dose display mechanism consisting of the said dose setting dial (22) and the counter ring (30) indicating the helical thread (111), rib grooves (64) and a preferred starting position of the counter ring (30). Figure 1 shows only one digit (66b) on the outer surface of the dose setting dial (22) for more clarity in accordance with the display window (62).

Figure 2a shows schematically a plan and perspective view of the counter ring (30). In this embodiment the counter ring (30) has unit numbers (66a) on the external surface. Preferably the interior diameter of the counter ring (30) is essentially the same size as the exterior diameter of the dose setting dial (22). Figure 2b indicates a preferred embodiment of the counter ring (30). The inner surface of the counter ring (30) is provided with ribs (63) formed, preferably, in the longitudinal axis and designed to mesh with rib grooves (64) located on the external surface of the dose setting dial (22) as indicated in Figure 1.

Figure 3 shows schematically a plan view of the dose setting dial (22). In this embodiment the dose setting dial (22) has tens numbers (66b) on the external surface, preferably arranged so that each single digit, e.g. 1, 2, 3, ..., 9, occurs ten times so that it corresponds with the counter ring during one full rotation of 360° to make a two-digit number, e.g. 10, 11, 12, ..., 19. A further full rotation of 360° will present two-digit numbers in the order 20, 21, 22, ..., 29. Further full rotations will yield corresponding two-digit numbers relating to 30's, 40's, 50's etc up to the maximum possible dose. The digits are preferably arranged helically on the outer surface of the dose setting dial (22) in a pitch corresponding to the pitch of the helical thread (111) of the dose setting dial (22). The helical thread (111) and the grooves (62) are not shown in Figure 3.

Figure 4 indicates a preferred embodiment of the dose display mechanism in a drug delivery device (1) showing the preferred position of the digits (66b) of the dose setting dial (22) and the digits (66a) of the counter ring (30) in the display window (62).

Figure 5 shows schematically a preferred embodiment of a drug delivery device in which the dose setting dial (22) and the counter ring (30) are assembled to a drive mechanism as disclosed in the co-application to this entitled "Drive mechanism for a drug delivery device", which is herewith incorporated by reference. In this embodiment the dose setting dial (22) is engaged with the housing (2) via the first screw structure (35), which incorporates the threaded insert (31). The dose setting dial (22) is free to rotate with respect to the housing (2) and also to move towards the proximal end during dose setting and towards the distal end during does delivery with respect to the housing (2). The counter ring (30) is prevented from axial movement towards the proximal end during dose setting and axial movement towards the distal end during dose dispensing with respect to the housing (2) by a positioning collar (65) preferably secured to the inner surface of the housing (2) and more preferably formed as an integral part of the housing (2). However the counter ring (30) is free to rotate with respect to the housing (2) due to its engagement with the dose setting dial (22).

Claims

1. A dose display mechanism for a drug delivery device comprising:
a dose setting dial having an external thread and external grooves extending from the proximal end to the distal end; and
a counter ring in an interlocking relationship with the external grooves of the said dose setting dial such that the said counter ring is free to move axially along said external grooves with respect to the said dose setting dial whilst being prevented from rotation with respect to the said dose setting dial.

2. A drug delivery device comprising
a) a drive mechanism and
b) the dose display mechanism as defined in claim 1.

3. The device according to claim 2 containing insulin, heparin, or any derivative or analogue thereof.

4. The use of the mechanism according to claim 1 for the assembly of a device according to any of claims 2 to 3.

5. The use of the mechanism according to claim 1 or a device according to any of claims 2 to 3 for the administration of a pharmaceutical formulation to the human or animal body.

6. The use according to claim 5, wherein the pharmaceutical formulation is selected form the group consisting of insulines, heparines, derivatives thereof and analogues thereof.

7. The method of assembling a drug delivery device, comprising the step of mounting the mechanism according to claim 1 to any other components in order to manufacture the drug delivery device according to any of claims 2 to 3.